

**REMARKS****I. Detailed Action**

A. Applicants are herein re-submitting for consideration by the Examiner a copy of the declaration of Dr. Yongli Xiao under 37 C.F.R. 1.131 originally submitted April 16, 2003.

B. Applicants acknowledge that the Examiner has acknowledged that the supplemental response dated April 16, 2003 has been entered. Additionally, Applicants acknowledge that the Office action mailed June 2, 2003 has been vacated by the Examiner.

C. Applicants acknowledge that the substitute drawings submitted January 21, 2003, in response to form PTO-948 have been approved by the Draftsperson

D. Applicants acknowledge that the objections to claims 6, 7, 9, 20, 22 and 23 are withdrawn, in light of the claim amendments made in the previous amendment.

E. Applicants acknowledge that the rejection of claims 18, 19 and 21 under 35 U.S.C. § 112, 2nd paragraph, is withdrawn in light of the claim amendments made in the previous amendment.

F. Applicants have added a new dependent claim 36 and ask the Examiner to consider it for allowance. No new matter has been added (see specification, p. 6).

**II. Priority**

The claim for domestic priority to provisional application 60/069,057 stands denied since the instant application was filed more than one year after the filing of the provisional.

Applicants traverse this denial. Applicants have amended the specification so that priority is claimed to both provisional application 60/069,057 as well as to U.S. Application No. 09/208,349 filed December 9, 1999. Priority was claimed to the provisional application when

the current application was filed. The priority claim to the intervening application was inadvertently omitted, and Applicants are now amending the specification to do so. This is appropriate due to the current application's filing date of October 20, 2000. Under 37 C.F.R. § 1.78(b)(ii)(B), the time periods enacted by the American Inventors Provision Act and established in 37 C.F.R. § 1.78(b)(ii) for claiming benefit from an earlier filing date which were are applicable to 35 U.S.C. § 111(a) applications filed after November 29, 2000. Since the current application was filed October 20, 2000, Applicants have not waived a priority claim and therefore may amend the specification to claim priority to U.S. Application No. 09/208,349 filed December 9, 1999. Additionally, all cases were properly co-pending at the time the current application was filed. Applicants therefore submit that due to the filing date of the currently application and the inadvertent omission of the priority claim to the intervening application, the amendment to the priority claim in the specification is proper.

### III. Claim Rejections

#### A. 35 U.S.C. § 112, second paragraph

Claims 1-10, 20 and 22-35 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 1, 5 and 8, the Examiner states that the term "introducing a transposase to the plant" is not clear because it is not known what is meant by this recitation. Applicants have amended the claims to include the Examiner's suggested language, thereby alleviating the rejection. Applicants wish to thank the Examiner for the suggested language.

With regard to claim 8, the Examiner states that the term "having homologous regions to a fragment of a gene" is indefinite. The Examiner further states that "[t]he recitation indicates

that only the coding sequences for a fragment of a gene are present, which indicates that a whole gene would not be generated upon recombination. This is not consistent with the last line of the claim . . . ."

Applicants have amended claim 8 to read:

A method to induce recombination in a plant comprising introducing to the plant a maize Ds element containing overlapping sequences having homologous regions to fragments of a gene, wherein said fragments together contain the complete gene; and expressing subsequently to the transformation of said Ds element a transposase within the plant, so as to induce homologous recombination and subsequent transcription of said complete gene.

As stated in the specification:

the entire sequence which encodes the construct product (or regulatory region) desired must be represented by the two fragments, and that the some of the same internal sequences must exist on each of the two fragments to produce a complete construct. (specification, p.7)

Therefore Applicants submit that claim 8 is now in allowable form because it makes clear that the gene fragments, upon recombination, will produce a complete gene construct and thereby allow for the "subsequent transcription of said complete gene."

With regard to claim 20, the Examiner states that the term "in a plant transformed with said construct" renders the claim indefinite. The Examiner further notes that it is not clear what is meant by "in a plant" and that there is insufficient antecedent basis for "said construct".

Applicants have amended claim 20 to clarify the meaning of the term "in a plant". Additionally, Applicants have amended claim 20 to read "A recombination construct comprising a DNA molecule, thereby alleviating this rejection. Therefore Applicants submit that claim 20 is now in allowable form.

With regard to claims 19, 20, 22 and 23, the Examiner states that the term "composition of matter" makes the metes and bounds of the claims unclear.

Applicants have amended claims 19 and 20 to read "A recombination construct comprising a DNA molecule". Applicants acknowledge that in the October 16, 2002 Office Action the Examiner stated that "DNA molecules can be induced to undergo homologous recombination." Applicants have canceled claim 22 to alleviate another rejection. Therefore Applicants submit that claims 19, 20, 22 and 23 are now in allowable form.

Claims 1-10 and 18-35 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regards to claim 1, the Examiner states that it "is indefinite because it does not indicate what is being induced to homologously recombine."

Applicants have amended claim 1 to clarify that the recombination construct introduced to the plant is being induced to homologously recombine. Furthermore, Applicants have also amended claim 1 to state "A method to induce homologous recombination of a nucleotide sequence" to further clarify what is being induced to homologously recombine. Applicants therefore submit that claim 1 is in condition for allowance.

With regard to claims 1, 5 and 8, the Examiner states that the terms "introducing a recombination construct to the plant" and "introducing to the plant" renders the claim indefinite.

Applicants have amended this term in claims 1, 5 and 8 in order to alleviate an earlier rejection with the Examiner's suggested language from that rejection. Applicants therefore submit that claims 1, 5 and 8 are in condition for allowance.

With regard to claims 6, 9, 25, 33 and 35, the Examiner states that the claims are indefinite for using improper Markush terminology.

Applicants have amended claims 6, 9, 25, 33 and 35 with the Examiner suggested deletion, thereby alleviating this rejection. Applicants wish to thank the Examiner for this suggestion.

With regard to claims 18-20, the Examiner states that the claims are indefinite because it is not clear what is undergoing recombination.

Applicants have amended the claims to read "A recombination construct comprising a DNA molecule which can be induced to undergo homologous recombination". Applicants acknowledge that in the October 16, 2002 Office Action the Examiner stated that "DNA molecules can be induced to undergo homologous recombination." Therefore Applicants submit that claims 18-20 are in condition for allowance.

With regard to claim 19, the Examiner states that the term "as part of vector" in the last line renders the claim indefinite. The Examiner further states that the metes and bounds of the claims are unclear.

Applicants have amended the claim to clarify the term "as part of a vector." Applicants submit that claim 19 is in condition for allowance.

With regard to claims 19, 20 and 24, the Examiner states the term "agronomically significant gene" is indefinite. The Examiner further states that it is not clear what type of genes are encompassed by this term.

Applicants respectfully traverse this rejection. As taught by the specification:

Preferred are those genes or sequences which are agronomically significant. For example, genes encoding male sterility, foreign organism resistance (viruses or bacteria), including genes which produce bacterial endotoxins, such as bacillus thuringiensis endotoxin, genes involved in specific biosynthetic pathways (e.g. in fruit ripening, oil or pigment biosynthesis, seed formation, or starch metabolism) or genes involved in environmental tolerance (e.g. salt tolerance, drought tolerance, or tolerance to anaerobic conditions). (specification, p. 10).

The specification thus teaches the meaning of the term "agronomically significant gene".

Applicants therefore submit that claims 19, 20 and 24 are in condition for allowance.

With regard to claim 22, the Examiner states the term "which further comprises a gene internal to said direct repeat sequences" renders the claim indefinite. The Examiner further states that parent claim 20 indicates that an agronomically significant gene is internal to the direct repeats and thus it is unclear if the gene mentioned in claim 22 is the same as the gene in claim 20.

Applicants have canceled claim 22, thereby alleviating this rejection.

*B. 35 U.S.C. § 112, first paragraph*

Claims 8-10 stand rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not describe in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner states that "the specification does not teach homologous recombination of overlapping sequences of gene fragments within a Ds element." Applicants acknowledge that the Examiner acknowledges that the specification does teach that the recombination events occur between homologous sequences comprising overlapping sequences of the GUS gene that flank the Ds element, and that the recombination occurs after Ds excision.

Applicants respectfully traverse this rejection. The test for enablement under § 112, first paragraph, is "whether or not the specification contains a sufficiently explicit disclosure to enable one having ordinary skill in the relevant field to practice the invention claimed therein without

the exercise of undue experimentation." Ex Parte Forman, 230 U.S.P.Q. 546 (Bd. Pat. App. & Int'l 1986).

Although the preferred embodiment is comprised of the Ds element flanked by the direct repeats, the specification clearly teaches that the location of the Ds element is not essential to the invention:

In all of the above aspects, the orientation of the Ds element and/or construct is not essential; either can be oriented in any manner. However, in all of the above aspects, it is preferable that the Ds element is between the direct repeats (for example, as in Fig. 1), although it is possible to induce recombination when the Ds element is within the direct repeats. (specification, p. 6).

Since the specification teaches that recombination may be induced when the Ds element is within the direct repeats rather than flanked by the direct repeats, one skilled in the art would not have to exercise undue experimentation in order to practice the invention. The specification therefore enables one skilled in the art to use and practice the invention.

*C. 35 U.S.C. § 102(b)*

Claims 1-4, 27 and 32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Shalev et al. The Examiner states Shalev teaches an assay for homologous recombination induced by the maize Ac transposase in transgenic tobacco plants. The plants were transformed with constructs containing the maize Ds element flanked by direct repeats. Recombination induced by Ac resulted in the combination of GUS deletion mutants to yield an intact, functional GUS gene.

Applicants respectfully traverse this rejection. 35 U.S.C. § 102(b) states that a patent may be anticipated by a publication printed more than one year prior to the filing date. Applicants have amended the specification to properly claim priority to U.S. Application No. 09/208,349

filed December 9, 1999 as well as to provisional application 60/069,057 filed December 10, 1997. Therefore, in order for a publication to qualify as 102(b) prior art, that publication must have been printed prior to December 10, 1996. Shalev et al. has a publishing date of July 1997. It thereby does not qualify as applicable 102(b) prior art. Claims 1-4, 27 and 32 are therefore not anticipated by Shalev et al.

Applicants are herein re-submitting for consideration by the Examiner the declaration of Dr. Yongli Xiao under 37 C.F.R. 1.131. Attached Exhibit A to the declaration is a copy of notebook records related to this conception wherein the construct used to measure recombination GU-US is disclosed. The notebook is dated January 28, 1996. Exhibit B is a copy of notebook records showing reduction to practice of the construct identified in Applicant's patent application. The notebook is dated June 9, 1997. Both of these exhibits pre-date the Shalev et al. article, which has a publishing date of July 1997.

*D. 35 U.S.C. § 103(a)*

Claims 1-10 and 18-35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Swoboda et al. in view of Shalev et al., Holtorf et al., Hain et al., and Fromm et al.

Applicants respectfully traverse this rejection. The test under § 103(a) is whether the differences between the prior art and the invention, as a whole, would have been obvious to one having ordinary skill in the art. *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 662 (Fed. Cir. 2000). The prior art must teach one of ordinary skill in the art to combine elements from the prior art in the manner combined by the inventor. *Crown Operations Int'l, Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 1376 (Fed. Cir. 2002). Thus, obviousness can not be determined by a hindsight gathering of elements in order to "fit the parameters" of the invention. *ATD Corp. v. Lydall, Inc.* 159 F.3d 534, 546 (Fed. Cir. 1998).



Shalev et al. does not constitute adequate prior art for reasons stated above. Applicants have amended the specification to properly claim priority to U.S. Application No. 09/208,349 filed December 9, 1999 as well as to provisional application 60/069,057 filed December 10, 1997. Moreover, Applicants are re-submitting for consideration by the Examiner the declaration of Dr. Yongli Xiao under 37 C.F.R. 1.131, which shows a date of conception as January 28, 1996, and a date of reduction to practice as June 9, 1997. Thus the Shalev et al. article, which has a publishing date of July 1997, is not appropriate prior art under § 103(a).

None of the individual references cited by the Examiner render Applicant's invention obviousness to one skilled in the art. Moreover, even if the references are combined, they do not teach one of ordinary skill in the art to combine elements from the prior art in the manner combined by the inventor. As noted by the Examiner in the Office Action dated October 16, 2002, Swoboda does not teach homologous recombination induced by a transposase or an inducible promoter, disease resistant genes, or transgenic maize plants. Additionally, Holtorf et al. only teaches heat shock promoters. Further, Hain et al. only teaches enhanced disease resistance against fungal infection in transgenic tobacco plants conferred by a grape stilbene synthase gene. None of these references, separate or combined, teach introducing to a plant a recombination construct which expresses a transposase, thereby inducing homologous recombination, wherein the recombination construct further comprises a transposase gene under the control of an inducible promoter, as is required by claims 1-10 and 18-35. Applicants therefore submit that claims 1-10 and 18-35 are nonobvious and in condition for allowance.

### III. Conclusion

In light of the above remarks, Applicants respectfully assert that claims 1-35 are now in condition for allowance. Applicants respectfully request reconsideration and withdrawal of the

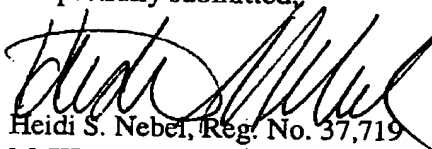
above rejections. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

This is a request under the provision of 37 CFR § 1.136(a) to extend the period for filing a response in the above-identified application for one month from January 7, 2004 to February 7, 2004. Applicant is a small entity; therefore, please charge Deposit Account number 26-0084 in the amount of \$55.00 for one month to cover the cost of the extension. Any deficiency or overpayment should be charged or credited to Deposit Account 26-0084.

No other fees are believed to be due in connection with this amendment; however, consider this a request for any inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

  
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